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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/471,040 | 12/23/1999 | ULF TILSTAM | SCH-1615-D1 | 6934 |

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EXAMINER

OWENS JR, HOWARD V

ART UNIT PAPER NUMBER

1623

DATE MAILED: 06/30/2004

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/471,040

Applicant(s)

TILSTAM ET AL.

Examiner

Howard V Owens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/24/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Response to RCE

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/24/04 has been entered.

An action on the merits of claims 5-16 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 5-16 are rejected under 35 U.S.C. § 103 as being unpatentable over Montgomery et al., U.S. Patent No. 4,357,324 and applicant's admission in the declaration (filed 8/28/03) that crystallization of fludarabine phosphate is known in the art.

Claims 5-16 are drawn to crystalline Fludarabine-phosphate with a purity ranging from at least 99.5% – 99.85%.

Montgomery discloses the same compound, Fludarabine-phosphate or 9-(5-O-phosphate-β-D-arabinofuranosyl)-2-fluoroadenine (claim 4 or columns 2-4). Montgomery isolates the Fludarabine-phosphate from other contaminants via HPLC (col.4, lines 4-6) with subsequent anion exchange chromatography purification. However, Montgomery does not specifically state that the purity of the compound was greater than 99.5% nor that the final form of the compound was crystalline.

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Although Montgomery does not specifically state the purity, when claiming a purer form of a known compound, it must be demonstrated that the purified material possess properties and utilities not possessed by the unpurified material, *Ex parte Reed*, 135 USPQ 34,36 (P.O.B.A. 1961). Furthermore, there exists a vast number of decisions holding that where the purification of an old product results in a mere change in its properties, the purified form is unpatentable, *Ex parte Windhaus*, 15 USPQ 45 (POBA 1931); *In re Ridgeway*, 76 F.2d 602, 25 USPQ 202 (CCPA 1935); *In re Merz*, 97 F.2d 599, 38 USPQ 143 (CPA 1938). The claims of the invention do not possess properties and utilities not possessed by the fludara compound disclosed in Montgomery. Applicant has asserted that the highest purity that could be obtained by Montgomery is 99.19%. There is only a .03% difference between that of Montgomery and the claimed purity, which is so insignificant that taking into account experimental error, the claimed composition remains obvious. Even if one of skill in the art is appraised of the low level of impurities present with current crystallization techniques, the claims at issue are not process claims, they are compound claims. As such, the distinction between applicant's compound based on a different process does not overcome obviousness with regard to claiming a known compound in a purer form.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to obtain the highest purity available or that commensurate to 99% or better.

A person of ordinary skill in the art would have been motivated to produce Fludarabine-phosphate at a purity of 99.5% or better to achieve the greatest anti-tumor efficacy. One of skill in the art would have had a reasonable expectation of success in the achievement of this purity given that the isolation of the compound had already been demonstrated in the prior art through routine purification techniques.

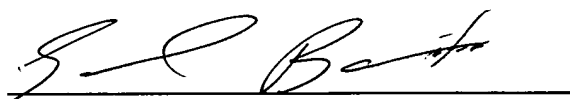
For the reasons cited above, the 35 U.S.C. 103 rejection of record is maintained.

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All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Howard V. Owens
Patent Examiner
Art Unit 1623

A handwritten signature in dark ink, appearing to read "S. Barts", is written over a horizontal line.

Samuel Barts
Primary Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658. The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.